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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/538,005 | 12/19/2006 | Jan Grund-Pedersen | 4145-000008/US | 6867 |
| 30593 7590 09/24/2009 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195 | | | | |
| EXAMINER | | | | |
| FRISBY, KESHA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3715 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,005

Applicant(s)

GRUND-PEDERSEN, JAN

Examiner

KESHA FRISBY

Art Unit

3715

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)
Paper No(s)/Mail Date 4/16/09, 6/27/05 & 6/3/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 1 & 4-13 contain black and shaded images, which are not permitted. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sheath recited in claim 4, per page 5 lines 17-19, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 1 & 6 are objected to because of the following informalities: "... value representing an stiffness of said ..." should be --... value representing a stiffness of said ...---. There should also be a colon (;) after the transitional phrase "comprising" to separate the preamble from the body of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites "... comprises a substantially double cone...". The examiner is unclear as to what "substantially" means in the context of this claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (U.S. Publication Number 2002/0168618).

Referring to claims 1 & 6, Anderson et al. discloses comprising a control unit (paragraphs 0123-0125) system processor) and an interface unit (paragraph 0114), said control unit communicating with said interface unit to simulate handling of at least one instrument interfaced by said interface unit (Figs. 1-4 & the associated text), wherein said instrument is a self expanding tool inserted inside a simulated vessel (paragraphs 0018 & 0036) and simulated with respect to a set value (paragraphs 0023 & 0037: physiological parameters and alter parameters). *Anderson et al. does not disclose a set value for representing an stiffness of said vessel, a rest diameter of said self expanding tool, a vessel initial inner diameter and spring constant for said tool.*

At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to have a set value for representing an stiffness of said vessel, a rest diameter of said self expanding tool, a vessel initial inner diameter and spring constant for said tool because Applicant has not disclosed that having a set value for representing an stiffness of said vessel, a rest diameter of said self expanding tool, a vessel initial inner diameter and spring constant for said tool

provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Anderson's system, and applicant's invention, to perform equally well with either the altering of parameters taught by Anderson or the claimed a set value for representing an stiffness of said vessel, a rest diameter of said self expanding tool, a vessel initial inner diameter and spring constant for said tool because both sets of parameters would perform the same function of altering the parameters in order to test or evaluate the system.

Therefore, it would have been prima facie obvious to modify Anderson to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Anderson.

Referring to claim 2, Anderson et al. discloses wherein said instrument is a stent (paragraphs 0018 & 0036).

Referring to claim 3, Anderson et al. discloses wherein said instrument is a distal protection device (simulated catheter & guidewire).

Referring to claim 4, Anderson et al. discloses wherein said distal protection device comprises a substantially double cone attached at two ends to a wire, and covered by a sheath (simulated catheter and guidewire).

Referring to claim 5, Anderson et al. discloses wherein a distal part of one cone is a net for simulating catching particles that can be set free during an intervention simulation (catheter/shaft).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Alexander et al. (U.S. Patent Number 6,929,481) teaches an interface device and method for interfacing instruments to medical procedure simulation systems.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KESHA FRISBY whose telephone number is (571)272-8774. The examiner can normally be reached on Monday-Friday 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kesha Frisby
Examiner
Art Unit 3715

/Kesha Frisby/
Examiner, Art Unit 3715 9/22/2009